REMARKS

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

Initially, applicant requests withdrawal of the restriction as it applies to method of use claims 24-25 and kit claims 26-27 and 31 that depend from claim 1.

The objection to claim 4 under 37 CFR § 1.75(c) for failing to limit the subject matter of a previous claim is respectfully traversed in view of the above amendments.

The rejection of claims 1, 2, 3, 10, 13, 20, and 32 under 35 U.S.C. § 102(b) as anticipated by Korth et al., "Prion (PrPSc)-specific Epitope Defined by Monoclonal Antibody," *Nature* 390:74-78 (1997) ("Korth I") is respectfully traversed.

Korth I discloses a monoclonal antibody ("mAb 15B3") that specifically precipitates bovine, murine, and human PrP^{Sc}, but not PrP^{C}. Korth teaches that mAb 15B3, raised against the full length recombinant bovine PrP, recognizes a conformational epitope consisting of three segments that correspond to amino acids 142-148 ("first segment"), 162-170 ("second segment"), and 214-226 ("third segment"), respectively, of the recombinant bovine PrP. The third segment of bovine PrP corresponds to SEQ ID No. 2 of the present invention, and the related third segment of human PrP corresponds to SEQ ID No. 1 of the present invention. Korth I does not teach or suggest whether any one of the segments alone is sufficient to raise antibodies capable of precipitating PrP^{Sc} but not PrP^{C} under non-denaturing conditions. In contrast, claim 1 of the present invention, as amended, is drawn to "[a] monoclonal antibody preparation comprising antibodies or fragments thereof capable of selectively binding to a three dimensional conformation provided by the C-terminal part of the PrP^{SC} isoform of the prion protein or a portion thereof, while not binding to the PrP^{C} isoform when both isoforms are present in a sample in a native, non-denatured state, wherein the monoclonal antibody preparation is raised against a peptide consisting essentially of SEQ ID No. 1 or SEQ ID No. 2." Because Korth teaches making a mAb selective for PrP^{Sc} using a full length recombinant bovine PrP peptide and does not teach or suggest that such a monoclonal antibody can be "raised against a peptide consisting essentially of SEQ ID No. 1 or SEQ ID No. 2," Korth I cannot anticipate the present invention.

Therefore, the rejection of claims 1, 2, 3, 10, 13, 20, and 32 under 35 U.S.C. § 102(b) as anticipated by Korth I is improper and should be withdrawn.

The rejection of claims 1, 2, 3, 5, 10, 12, 13, 20, and 32 under 35 U.S.C. § 102(b) as anticipated by EP 0 861 900 A1 to Korth et al. ("Korth II") is respectfully traversed.

Korth II discloses the same monoclonal antibody, i.e., mAb 15B3, as Korth I. Therefore, Korth II cannot anticipate the present invention as amended for substantially the same reasons as described in the discussion of the rejection over Korth I, above. Accordingly, the rejection of claims 1, 2, 3, 5, 10, 12, 13, 20, and 32 under 35 U.S.C. § 102(b) as anticipated by Korth II is improper and should be withdrawn.

The rejection of claims 1, 2, 4, 5, 12, 13, and 20 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,846,533 to Prusiner ("Prusiner") is respectfully traversed. Although applicant disagrees with the interpretation of Prusiner adopted by the U.S. Patent and Trademark Office ("PTO"), applicant submits that Prusiner fails to teach or suggest a monoclonal antibody preparation that has been "raised against a peptide consisting essentially of SEQ ID No. 1 or SEQ ID No. 2." Therefore the rejection of claims 1, 2, 4, 5, 12, 13, and 20 as anticipated by Prusiner is improper and should be withdrawn.

The rejection of claims 1-5, 12, 13, and 20 under 35 U.S.C. § 112 (1st para.) for lack of enablement is respectfully traversed.

It is the position of the PTO that the specification, while enabling for the specifically disclosed antibody produced by the CNCM-I-2476 hybridoma, does not provide enablement for any other antibodies that bind preferentially to the disease specific form of the prion specific structure. Applicant respectfully disagrees.

Applicant would like to draw the attention of the PTO to the fact that claim 1 now specifies that the "monoclonal antibody preparation is raised against a peptide consisting essentially of SEQ ID No. 1 or SEQ ID No. 2." Given this amendment, applicant submits the specification provides sufficient disclosure regarding the preparation of such antibodies that a skilled scientist, having read the present application, would be fully capable of making additional antibodies that bind preferentially to the disease specific form of the prion specific structure.

In particular, the present application teaches that antibodies capable of binding to the critical three dimensional "misfolded" structure of the PrP^{Sc} can be obtained by selecting a peptide as recited in claim 1 (page 6, lines 8-24) and then proceeding as taught in

the specification. That the presently claimed invention is fully enabled is supported Korth I and Korth II. As noted above, Korth I and Korth II disclose monoclonal antibody 15B3, which was raised against full length recombinant bovine PrP protein and shown to precipitate bovine, murine, and human PrP^{Sc}, but not PrP^{C}. Korth I and Korth II further show that the peptides of SEQ ID Nos. 1 and 2 represent one of three segments of a conformational epitope for PrP^{Sc} binding. Furthermore, applicant submits that the production of antibodies is well-known to those of ordinary skill in the art.

Thus, applicant submits that an individual skilled in the art, armed with the knowledge of one of ordinary skill in the art, and having read the present application and raised antibodies against a peptide consisting essentially of SEQ ID No. 1 or SEQ ID No. 2, would be fully able to make a monoclonal antibody preparation that includes monoclonal antibodies or fragments thereof capable of selectively binding to a three dimensional conformation provided by the C-terminal part of the PrP^{SC} isoform of the prion protein or a portion thereof, while not binding to the PrP^{C} isoform when both isoforms are present in a sample in a native, non-denatured state.

For these reasons, the rejection of claims 1-5, 12, 13, and 20 for lack of enablement is improper and should be withdrawn.

In view of all of the foregoing, applicant submits that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450, on the date below.

March 3, 2004 — Jo Ann Whalen
Date — Jo Ann Whalen